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EXAMINER

DECLoux, AMY M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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B-A-C

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# Office Action Summary

Application No.

09/766,378

Applicant(s)

Rhode et al

Examiner

DeCloux, Amy

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☐ Responsive to communication(s) filed on \_\_\_\_\_

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☒ Claims 1-37 are subject to restriction and/or election requirements.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20) ☐ Other: \_\_\_\_\_

### Detailed Action

1. A restriction is required under 35 USC 121 between one of the following groups:

I. Claims 1-4, drawn to an empty sc-MHC class II molecule comprising a peptide binding groove and a class II  $\beta$ 2 chain comprising at least one amino acid substitution or deletion, classified in class 530, subclass 350,

II. Claims 5-6, drawn to a sc-MHC class II molecule comprising a peptide binding groove and a class II  $\beta$ 2 chain comprising at least one amino acid substitution or deletion, classified in class 530, subclass 350,

III. Claim 7, drawn to a sc-MHC class II fusion protein comprising a recombinantly fused presenting peptide and a covalently linked immunoglobulin light chain constant region or fragment, classified in class 435, subclass 69.7,

IV. Claims 8-10 and 14, drawn to an empty sc-MHC class II molecule comprising a peptide binding groove, wherein the molecule comprises covalently linked in sequence an MHC class II  $\beta$  chain or a presenting-peptide binding portion thereof, a class II  $\beta$ 2 chain, comprising at least one amino acid substitution or deletion, a peptide linker and an MHC class II  $\alpha$ 1  $\alpha$ 2 chain or presenting peptide binding portion thereof, classified in class 530, subclass 350,

V. Claims 11-14, drawn to an empty sc-MHC class II molecule comprising a peptide-binding groove, wherein the molecule comprises covalently linked in sequence an MHC class II  $\beta$ 1  $\beta$ 2 chain or a presenting-peptide binding portion thereof, a peptide linker sequence, an MHC class II  $\alpha$ 1  $\alpha$ 2 chain or presenting-peptide binding portion thereof, classified in class 530, subclass 350,

VI. Claims 15-20, drawn to a sc-MHC class II fusion protein comprising a peptide binding groove, the sc-MHC class II fusion molecule comprising covalently linked in sequence a presenting peptide, and MHC class II  $\beta$ 1 chain or a presenting-peptide binding portion thereof, an MHC class II  $\beta$ 2 chain comprising at least one amino acid substitution or deletion, a peptide linker sequence and an MHC Class II  $\alpha$ 1  $\alpha$ 2 chain or a presenting-peptide binding portion thereof, classified in class 435, subclass 69.7,

VII. Claims 21, 22 and 24, drawn to a sc-MHC class II fusion molecule comprising a peptide-binding groove, wherein the fusion molecule comprises covalently linked in sequence: a presenting peptide, and MHC class II  $\beta$ 1  $\beta$ 2 chain or a presenting-peptide binding portion thereof, a peptide linker sequence, an MHC class II  $\alpha$ 1  $\alpha$ 2 chain a presenting-peptide binding portion thereof and an immunoglobulin light chain constant region or fragment, classified in class 435, subclass 69.7,

VIII. Claims 21, 23 and 24, drawn to an empty sc-MHC class II fusion molecule comprising a peptide-binding groove, wherein the fusion molecule comprises covalently linked in sequence: a presenting peptide, and MHC class II  $\beta 1 \beta 2$  chain or a presenting-peptide binding portion thereof, a peptide linker sequence, an MHC class II  $\alpha 1 \alpha 2$  chain a presenting-peptide binding portion thereof and an immunoglobulin light chain constant region or fragment, classified in class 435, subclass 69.7,

IX. Claims 25 and 27, drawn to an empty polyspecific MHC complex comprising an sc-MHC class following general formula A-B1-C1

D-B2-C2

wherein C1 and C2 are the same and B1 and B2 are the same, classified in class 530, subclass 350,

X. Claims 25 and 27, drawn to an empty polyspecific MHC complex comprising an sc-MHC class following general formula A-B1-C1

D-B2-C2

wherein C1 and C2 are the same and B1 and B2 are different, classified in class 530, subclass 350,

XI. Claims 25 and 27, drawn to an empty polyspecific MHC complex comprising an sc-MHC class following general formula A-B1-C1

D-B2-C2

wherein C1 and C2 are different and B1 and B2 are the same, classified in class 530, subclass 350,

XII. Claims 25 and 27, drawn to an empty polyspecific MHC complex comprising an sc-MHC class following general formula A-B1-C1

D-B2-C2

wherein C1 and C2 are different and B1 and B2 are different, classified in class 530, subclass 350,

XIII. Claims 26-27, drawn to a polyspecific MHC complex comprising an empty sc-MHC class II molecule comprising a peptide binding groove, the complex being represented by the formulae A-B-C, classified in class 530, subclass 350,

XIV. Claims 26-27, drawn to a polyspecific MHC complex comprising an empty sc-MHC class II molecule comprising a peptide binding groove, the complex being represented by the formulae B-A-C, classified in class 530, subclass 350,

XV. Claims 26-27, drawn to a polyspecific MHC complex comprising an empty sc-MHC class II molecule comprising a peptide binding groove, the complex being represented by the formulae A-C-B, classified in class 530, subclass 350,

XVI. Claim 28, drawn to a polyspecific MHC complex fusion molecule comprising an sc-MHC molecule with peptide binding groove, the complex being represented by the following formula A-B1-C1

D-B2-C2

wherein C1 and C2 are the same and B1 and B2 are the same, classified in class 435, subclass 69.7,

XVII. Claim 28, drawn to a polyspecific MHC complex fusion molecule comprising an sc-MHC molecule with peptide binding groove, the complex being represented by the following formula A-B1-C1

D-B2-C2

wherein C1 and C2 are the same and B1 and B2 are different, classified in class 435, subclass 69.7,

XVIII. Claim 28, drawn to a polyspecific MHC complex fusion molecule comprising an sc-MHC molecule with peptide binding groove, the complex being represented by the following formula A-B1-C1

D-B2-C2

wherein C1 and C2 are different and B1 and B2 are different, classified in class 435, subclass 69.7,

XIX. Claim 28, drawn to a polyspecific MHC complex fusion molecule comprising an sc-MHC molecule with peptide binding groove, the complex being represented by the following formula A-B1-C1

D-B2-C2

wherein C1 and C2 are different and B1 and B2 are the same, classified in class 435, subclass 69.7,

XX. Claim 29, drawn to a polyspecific MHC fusion molecule comprising a sc-MHC class II molecule comprising a peptide binding groove, the complex being represented by the formula A-B-C, classified in class 435, subclass 69.7,

XI. Claim 29, drawn to a polyspecific MHC fusion molecule comprising a sc-MHC class II molecule comprising a peptide binding groove, the complex being represented by the formula B-A-C, classified in class 435, subclass 69.7,

XII. Claim 29, drawn to a polyspecific MHC fusion molecule comprising a sc-MHC class II molecule comprising a peptide binding groove, the complex being represented by the formula A-C-B, classified in class 435, subclass 69.7,

XIII. Claim 30, drawn to a DNA segment encoding the sc-MHC molecule of claims 1 or 3,

XIV. Claim 30, drawn to a DNA segment encoding the sc-MHC molecule of

claim 5, classified in class 536, subclass 23.1,

XV. Claim 30, drawn to a DNA segment encoding the sc-MHC molecule of claim 7, classified in class 536, subclass 23.1,

XVI. Claim 31, drawn to a DNA segment encoding at least of portion of the polyspecific MHC molecule of claim 22, classified in class 536, subclass 23.1,

XVII. Claim 31, drawn to a DNA segment encoding at least of portion of the polyspecific MHC molecule of Group XIII, classified in class 536, subclass 23.1,

XVIII. Claim 31, drawn to a DNA segment encoding at least of portion of the polyspecific MHC molecule of Group XIV, classified in class 536, subclass 23.1,

XIX. Claim 31, drawn to a DNA segment encoding at least of portion of the polyspecific MHC molecule of Group XV, classified in class 536, subclass 23.1,

XXX. Claim 32, drawn to a vector comprising the DNA segments of claim 27, classified in class 435, subclass 320.1,

XXXI. Claim 33, drawn to a vector comprising the DNA segments of claim 29, classified in class 435, subclass 320.1,

XXXII. Claims 34-35, drawn to a method of manufacturing a sc-MHC class II molecule comprising a  $\beta 2$  class II chain modification, the method comprising DNA sequence encoding the sc-MHC class II molecule comprising the  $\beta 2$  class II chain modification, encompassed by the sc-MHC class II molecule of claims 1 and 3, classified in class 435, subclass 69.1,

XXXIII. Claims 34-35, drawn to a method of manufacturing a sc-MHC class II molecule comprising a  $\beta 2$  class II chain modification, the method comprising DNA sequence encoding the sc-MHC class II molecule comprising the  $\beta 2$  class II chain modification, encompassed by the sc-MHC class II molecule of claim 5, classified in class 435, subclass 69.1,

XXXIV. Claims 34-35, drawn to a method of manufacturing a sc-MHC class II molecule comprising a  $\beta 2$  class II chain modification, the method comprising DNA sequence encoding the sc-MHC class II molecule comprising the  $\beta 2$  class II chain modification, encompassed by the sc-MHC class II molecule of claim 7, classified in class 435, subclass 69.1,

XXXV. Claim 36, drawn to a method of manufacturing a polyspecific MHC Class II complex of Group XIII, classified in class 435, subclass 69.1,

XXXVI. Claim 36, drawn to a method of manufacturing a polyspecific MHC Class II complex of Group XIV, classified in class 435, subclass 69.1,

XXXVII. Claim 36, drawn to a method of manufacturing a polyspecific MHC Class II complex of Group XV, classified in class 435, subclass 69.1,

XXXVIII. Claim 37, drawn to a method of suppressing an immune response in a mammal comprising administering the sc-MHC complex of claim 4, classified in class 424, subclass 184.1,

XXXIX. Claim 37, drawn to a method of suppressing an immune response in a mammal comprising administering the sc-MHC complex of claim 5, classified in class 424, subclass 184.1,

XL. Claim 37, drawn to a method of suppressing an immune response in a mammal comprising administering the sc-MHC complex of claim 7, classified in class 424, subclass 184.1,

XLI. Claim 37, drawn to a method of suppressing an immune response in a mammal comprising administering the sc-MHC complex of claim 17, classified in class 424, subclass 184.1,

XLII-XLV. Claim 37, drawn to a method of suppressing an immune response in a mammal comprising administering the sc-MHC complex of groups XVI-XIX, respectively, classified in class 424, subclass 184.1,

Note: each claim will be examined only to the extent of the elected invention,

The inventions are distinct, each from the other because:

2. Groups XXXII- XLV are unique methods, because each method has a different endpoint and/or comprises different method steps and/or comprises different ingredients. Therefore, Groups XXXII- XLV are patentably distinct.

3. Groups I-XXXI are unique products, because each product has a different structure with distinct biophysical properties. Therefore, Groups I-XXXI are patentably distinct.

4. Groups XXXII-XXXVII and Groups I/II/III/XIII/XIV/XV, respectively, are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another

and materially different process (MPEP § 806.05(f)). In the instant case, the products, can be made by synthetic protein synthesis techniques, as well as genetic recombinant techniques.

5. Groups I/II/III/VI/XVI-XIX and Groups XXXVIII/XXXIX/XL/XLI/XLII-XLV, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, can be used as in a method of affinity purification, as well as in the recited methods.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search in the non-patent literature of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

5. A) Regardless of which group is elected, applicant is further required under 35 U.S.C. 121:

to elect a product or method comprising a molecule with a **specific MHC Class II  $\alpha$  chain**, and a **specific MHC Class II  $\beta$  chain**,

B) If group I/II/VI/XIII/XIV/XXXII/XXXIII/XXXVIII/XXXIX/XLI is elected, the applicant is further required:

to elect a product or method comprising a molecule with a **specific substitution and/or deletion**,

6. Claims 1-37 are generic in at least one aspect.

7. The species are distinct each from the other for the following reasons:

A) Proteins consisting of distinct amino acid sequences differ with respect to their biochemical structure and function,

B) MHC Class II molecules consisting of distinct amino acid sequences differ with respect to their biochemical structure and function.

8. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.



9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers (**other than elections**) should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.  
Patent Examiner  
Group 1640, Technology Center 1600  
March 25, 2002

*Amy De Cloux*  
3-25-02